

C.S. B5: A Physician Survey with Links to Patient Data in Secondary Datasets

Overview

The objective of this study is to evaluate the validity and reliability of an instrument that classifies physicians into four groups according to how they prefer to implement new research findings about the effectiveness of clinical practices. This instrument could then be used to tailor the design of guideline implementation efforts to particular types of physicians.

Subjects & Sample Size

Subjects are primary care physicians at 42 VAMCs.

Data Collection

Physicians receive a baseline survey mailed to their VAMC addresses, and those who respond receive a follow-up survey 1 year later. The 17-item, one-page survey asks questions about how the respondent incorporates research findings into clinical practice, and what other factors influence her/his practice.

A study identification number is assigned to each participating physician and a list linking the ID number with the physician's Social Security Number is maintained in a password-protected,

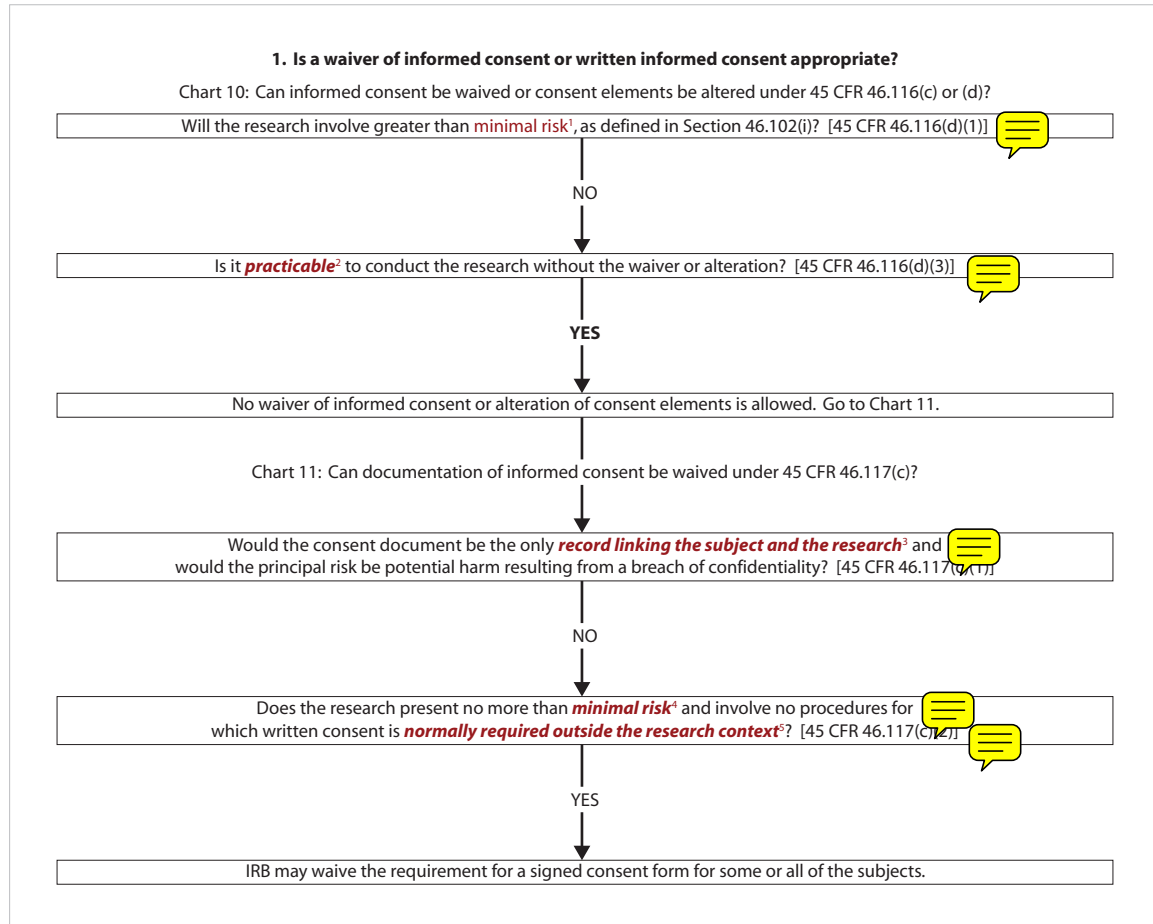
electronic file on a secure computer drive, which is separate from the drive in which the study data are maintained. This link is needed for linking the survey data to pharmacy, blood pressure, and diagnostic data in secondary VA administrative and clinical databases. The data will be analyzed to determine the extent to which physicians comply with established guidelines for treating high blood pressure in patients with diabetes, and for linking this compliance with physician type, as determined by physician responses to the survey. No individual provider data will be reported.

The following questions address only the physicians as subjects, not the patients whose data (from the secondary databases) are also included in the study. (The use of patient data should also be reviewed by the IRB for consent and privacy issues—see Case Study B1 for guidance in this area.)

Questions:

1. Is a waiver of informed consent or written informed consent appropriate? [[Link](#)]
2. Is a waiver of HIPAA authorization appropriate? [[Link](#)]

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[From OHRP Web site: www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm]

Notes for C.S. B5: Q1

¹Definition: “Minimal risk means that the *probability* and *magnitude* of harm or discomfort anticipated in the research are not greater in and of themselves than those *ordinarily encountered in daily life* or during the performance of routine physical or psychological examinations or tests” (CFR 46.102(1)).

Discussion: All panel members felt that this study is most likely minimal risk. The major risk to the physician of participating in this study is potential loss of confidentiality. The panel felt that the *probability and magnitude* of loss of confidentiality are no greater than *that which is encountered in daily life*. Even though data on participants’ compliance with practice guidelines could be used to monitor their performance and, in turn, be used to adversely affect their evaluations or even jeopardize their employment, the probability of this happening is not any greater than the existing probability of the data being used for these purposes. These data are routinely collected, reported, and reviewed by upper level management for purposes of performance evaluation.

The small probability of loss of confidentiality is based on the assumption that the safeguards for maintaining data confidentiality by the investigators are sufficient and are as good as those used elsewhere in the health care facility for ensuring the confidentiality of pro-

vider performance data. Therefore, the protocol must include a sufficient explanation of the procedures for maintaining data confidentiality.

Two of the panel members felt that the study potentially posed greater than minimal risk, because of the potential for jeopardizing the participants’ employment if there was a breach in confidentiality and if the data revealed a participant’s poor performance in adhering to practice guidelines. A third member of the panel was also equivocal—not so much from concern with revealing a participant’s degree of adherence to practice guidelines (s/he agreed these data are routinely obtained and reported)—but because of concern with the potential for stigmatizing the participants based on their responses to the survey. I.e., in classifying a respondent according to the way s/he implements new research findings, the findings might be viewed as negatively characterizing a respondent. A breach in confidentiality of the findings could then adversely affect others’ perceptions of the respondent(s). The IRB must consider the potential magnitude for harm if such a breach occurred. In considering the probability of a breach in confidentiality, the IRB must look not only at the safeguards in place for storing data, but also how the data will be reported. If the sample size at a site is particularly small and data are reported on a site-specific basis, it may be possible to ascribe data to a particular provider.

Notes for C.S. B5: Q1 (cont.)

²**Definition:** It is practicable to obtain informed consent by providing participants with an information sheet accompanying the survey.

³**Definition:** The investigators are maintaining a file of identifiers that can be linked to the subjects.

⁴**Definition:** “Minimal risk means that the *probability* and *magnitude* of harm or discomfort anticipated in the research are not greater in and of themselves than those *ordinarily encountered in daily life* or during the performance of routine physical or psychological examinations or tests” (CFR 46.102(1)).

Discussion: The majority of panel members considered this study to be minimal risk. However, three members disagreed (with a fourth being equivocal), and considered the study to be greater than minimal risk. See discussion for note #1.

⁵**Discussion:** The majority of the panel felt that the study involved no procedures for which written consent is normally required outside the research context.

2. Is a waiver of HIPAA authorization appropriate?

Yes. The majority of the panel felt that a waiver of HIPAA authorization is appropriate, because no health information is being collected on the participating physicians. (Note: a discussion of informed consent and HIPAA authorization for the patient data are not discussed here. See Case Study B1 for guidance in this area.)